This summary of 510(k)-safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

Date Prepared: October 12, 2000

510(k) number: **K003249**

Applicant Information:
PST, Inc.
2462 Embarcadero Way
Palo Alto, CA 94303

Contact Person: William Nadel
Phone Number: (650) 849-2000
Fax Number: (650) 849-2005

Device Information:
Classification: Class II
Trade Name: PST Electrosurgical System
Classification Name: Electrosurgical Device and accessories (21 CFR 870.4400)

Equivalent Device:
The subject device is substantially equivalent in intended use and/or method of operation to the Circon Tripolar Cutting Forceps (K932293), the Valleylab Force FX Electrosurgical Generator (K944602), and the Valleylab Ligasure Vessel Sealing System (K981916).

Intended Use:
The PST Electrosurgical System is intended for use in general, laparoscopic, and gynecologic procedures where grasping, coagulation and transection of tissues and vessels are desired. This device is not intended for contraceptive tubal coagulation (permanent female sterilization).

Test Results:
Performance
Results of bench and animal testing demonstrate that the PST Electrosurgical System is safe and effective for its intended function.

Biocompatibility
The patient contacting materials used in the PST Endoscopic Bipolar Forceps have been shown to be biocompatability when tested in accordance with ISO 10993-1 requirements.

Summary:
Based on the intended use, product, performance and biocompatability information provided in this notification, the subject device has been shown to be substantially equivalent to the currently marketed predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 12 2000

Mr. William Nadel
Managing Director
PST, Inc.
2462 Embarcadero Way
Palo Alto, California 94303

Re: K003249
Trade Name: PST Electrosurgical System
Regulatory Class: II
Product Code: GEI
Dated: October 12, 2000
Received: October 17, 2000

Dear Mr. Nadel:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

for Mark N Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K003249

Device Name: PST Electrosurgical System

Indications for Use:

The PST Electrosurgical System is intended for use in general, laparoscopic, and gynecologic procedures where grasping, coagulation and transection of tissues and blood vessels are desired. This device is not intended for contraceptive tubal coagulation (permanent female sterilization).

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N Milhern

(Division Sign-Off)
Division General Restorative Devices
510(k) Number K003249 12/12/00

Prescription Use ✓ OR Over-the Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)